IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION	§	MDL Case No. 2004
	§	
	§	Individual Case No. 4:11-CV-5065-CDL (Morey, Irene)
	§	
	§	Individual Case No. 4:11-CV-5075-CDL (Riley, Sharon and Leland)

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT MENTOR WORLDWIDE LLC'S MOTION *IN LIMINE* NO. 4: MOTION TO EXCLUDE ADMISSION OF ADVERSE EVENT REPORTS OR COMPLAINT FILES

I. INTRODUCTION

The Court should deny Mentor Corporation's Motion *in Limines* 4 because:

(1) The issues herein have already been ruled upon in Plaintiffs' favor, which is now the law of the case;

(2) The adverse event reports and complaint files are not hearsay;

(3) Multiple exceptions would apply even if the adverse event reports and complaints were hearsay;

(4) The probative value of the adverse event reports and complaint files is substantial and their admission would not unfairly prejudice Defendant; and

(5) The adverse event data in both the adverse event reports and complaint files is substantially similar to Plaintiffs' cases.

II. ARGUMENT

A. The Issues Herein Have Already Been Ruled Upon In Plaintiffs' Favor

To the extent that MIL 4 overlaps with the previous MIL 14 filed by Defendants in 2010, this Court's rulings are the law of the case and control. *Oladeinde v. City of Birmingham*, 230 F.3d 1275, 1288 (11th Cir. 2000).

In 2010, this Court ruled that adverse event reports were admissible. (Exh. A - Dkt. 302). On the issue of the admission of subsequent incidents of ObTape complications, the court conclusively stated, "[t]he Court finds that subsequent incidents of ObTape complications that are substantially similar to those experienced by Plaintiffs may be admissible at trial." (Exh. A - p. 1). Curiously, Mentor has now cited the very authority the court relied on in its 2010 ruling. "[E]vidence of similar occurrences may be offered to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." (Exh. A p. 3 citing *Hessen v. Jaguar Cars*, 915 F.2d 641, 650 (11th Cir. 1990)).

The Court has already rejected Defendant's argument. The admissibility of this critical evidence has already been established.

B. The Adverse Event Reports and Complaint Files Are Not Hearsay

1. They Are Not Offered For A Hearsay Purpose

Evidence not offered for a hearsay purpose is not hearsay and therefore, cannot be excluded under the hearsay rules. *United States v. Bailey*, 270 F.3d 83 (1st Cir. 2001). A hearsay statement includes any statement that is offered to assert the truth of such statement. Fed. R. Evid. 801(c)(2). If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, and the statement is not hearsay. *Emich*

Motors Corp. v. General Motors Corp., 181 F.2d 70 (7th Cir. 1950) (rev'd on other grounds). Defendant misplaces its reliance on cases where adverse event reports were offered for the sole purpose of causation. (*See, Appleby v. Glaxo Wellcome, Inc.*, 2005 WL 3440440 (D. NJ 2005); (*Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194 (11th Cir. 2002) (where evidence of unspecified FDA documents was inadmissible for the purpose of causation); *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F. Supp. 2d 434 (W.D. Penn. 2003) (where adverse drug event reports were not admissible to prove only causation); *see also, Hessen* (allowing evidence of prior automobile accidents of cars identical to the one at issue for the intended purposes of notice, magnitude, ability to recall, etc.)).

Here, however, the adverse event reports and complaint files are relevant to and offered as evidence of:

(1) Notice: many physicians were expressing alarm at what they identified as high rates of erosion and infection;

(2) failure to investigate reports: Mentor failed to follow up on these complaints;

(3) failure to test: Mentor did not conduct studies regarding the underlying causes of these reported erosions and infections;

(4) failure to recall: The complaints show that physicians were rejecting ObTape as dangerously defective, yet Mentor did not follow suit;

(5) failure to fulfill reporting obligations to the FDA: The complaint files show discrepancies between the information received by Mentor and the information Mentor reported to the FDA;

(6) failure to promulgate adequate warnings: The complaint files reveal physicians' surprise at the high rates and severity of complications from ObTape;

(7) notice of existence of a defect: Based on the high rates of failure; and

(8) punitive damages: Based on notice, the volume of information available to Mentor, and Mentor's dismissive attitude toward complaints as revealed by its internal communications and attempts to appease, rather than question, the

alarmed physicians.

The foregoing purposes underlying the relevance of the adverse event reports and complaint files are not hearsay purposes. They are not being offered for the purposes of establishing that any one particular adverse event happened on one particular date in a manner described by any one particular physician. To the contrary, they are being offered for the relevant and admissible purposes Plaintiffs outline here. (*See, In re PPA Products Liability Litigation*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003); *Ramos v. Liberty Mutual Ins. Co.*, 615 F.2d 334 (5th Cir. 1980)). Therefore, the reports and complaints are not hearsay; they are admissible.

2. Opposing Party Statements

Rule 801(d) defines statements that are not hearsay. Specifically, Federal Rule of Evidence 801(d)(2) states that a statement offered against an opposing party that meets the following criteria is not hearsay:

> (A) [the statement] was made by the party in an individual or representative capacity;
>
> (B) [the statement] is one the party manifested that it adopted or believed to be true;
>
> (C) [the statement] was made by a person whom the party authorized to make a statement on the subject;
>
> (D) [the statement] was made by the party's agent or employee on a matter within the scope of that relationship and while it existed…

Fed. R. Evid. 801(d)(2).

Mentor's argument that certain items of Plaintiffs' adverse event report evidence are hearsay disregards that the vast majority of Plaintiffs' evidence comes directly from Mentor's own ObTape "product evaluation" files. Adverse event reports and complaint files are *created and maintained by Mentor and its sales representatives*, not physicians, for the mixed purpose of marketing, and fulfilling Mentor's reporting duties to the FDA.

Each complaint file contains the following:

1. "Field Experience Report Form," *created* by Mentor, and developed by its marketing division. These forms are *filled out by the Mentor sales department*.
2. "MedWatch" mandatory device reporting (MDR) form. This form is *filled out by Mentor* and sent to the FDA. Generally, for each file, the information Mentor provides (through the MDR) to the FDA is much less detailed than the initial information gathered by the sales rep.
3. "Incident Information" worksheet, *filled out by Mentor*, which attempts to classify the incident in terms of its reporting requirements.
4. Some files also contain informal e-mail or written correspondence between Mentor and the device user (often the device user expressing alarm at the high rate of erosions, and Mentor attempting to alleviate those concerns).

Plaintiffs are offering all adverse event reports and complaint files against the very party that authored them—Defendant Mentor. Because Mentor is a party to this case and the adverse event reports and complaint files were created and maintained by Mentor, those reports and complaints satisfy Rule 801(d)(2).

C. Many Hearsay Exceptions Would Otherwise Apply

The evidentiary rules for hearsay allow many exceptions to statements that would otherwise constitute hearsay. Fed. R. Evid. 803. Although the data contained in the adverse event reports and complaint files unequivocally is not hearsay, they would nonetheless qualify for multiple hearsay exceptions.

1. Rule 803(4)

Federal Rule of Evidence 803(4) spells out the 'purpose of medical treatment/diagnosis' exception to hearsay. That is, "a statement that is made for – and is reasonably pertinent to – medical diagnosis or treatment; and describes medical history; past or present symptoms or sensations; their inception; or their general cause is not excluded by the rule against hearsay".

Fed. R. Evid. 803(4).

Complaints include reports of injuries after the use of medical devices. 21 C.F.R. § 820.3(b) (complaints are, "any written, electronic, or oral communication that alleges *deficiencies* related to the identity, *quality, durability*, reliability, *safety*, effectiveness, or *performance* of a device after it is released for distribution). Adverse event reports and complaint files then, by their nature, include the reporting of medical problems that have occurred after the use of a medical device. Defendant Mentor correctly states, "FDA regulations further require device manufacturers to report adverse events involving medical devices when the manufacturer becomes aware of information that reasonably suggests that the device caused or contributed to a *serious injury*…" MIL 4 p. 1-2.

As described above, the past medical records/diagnosis exception to hearsay includes any statement that is pertinent to the inception of a medical condition. Both the adverse event reports and complaint files describe past symptoms or sensations and their inception, and would, thus, satisfy this exception.

2. Rule 803(6)

Federal Rule of Evidence 803(6) describes the 'business records' exception. Defendant incorrectly states that the business records exception does not apply because there is hearsay within hearsay in both the reports and the complaints. They conclude that there needs to be a hearsay exception that applies to the adverse event data supplied by the initial reporter. The final reports, however, which is the evidence Plaintiffs seek to offer, are created and maintained by Mentor and its employees. Because the statements contained in both reports and complaints are those of Mentor and its employees, there need be only one hearsay exception met.

The elements of a business records hearsay exception are:

(A) The record was made at or near the time by – or from information transmitted by – someone with knowledge;

(B) The record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;

(C) Making the record was a regular practice of that activity;

(D) All these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and

(E) Neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid. 803(6).

Both the adverse event reports and complaint files meet every element of the business records exception.

3. Rule 807

Rule 807 is the residual hearsay exception. Both adverse event reports and complaint files would certainly fit within the residual exception under Rule 807 because these internal corporate records are undeniably trustworthy (again, the company itself relied on these records in conducting its business, and it certainly relies on them in its defense of these cases), and they are more probative of the points for which they are offered (magnitude and frequency of danger/defect, causation, lack of safety and standard of care). Fed. R. Evid. 807.

D. <u>The Probative Value Of The Adverse Event Reports And Complaint Files Substantially Outweighs The Danger of Unfair Prejudice</u>

The heart of Defendant's Rule 403 argument is that the "adverse event report data would be unfairly prejudicial, misleading, and confusing to the jury." MIL 4 p. 6. The cited authority Defendant Mentor relies upon for its Rule 403 argument is misguided. Defendant does not provide a single case where adverse event reports offered for something other than, or in tandem with, causation were found inadmissible because the danger of unfair prejudice outweighed the probative value. Instead, Defendant again relies on cases where causation is the only purpose for which Plaintiffs offer adverse event report evidence.

Defendant cites *Rider v. Sandoz*, for the proposition that the court found the case reports

offered by Plaintiffs to be "merely accounts of medical events". While Defendant's citation is literally accurate, reading the case as a whole indicates that the court ultimately disallowed the report evidence because Plaintiffs offered it as purely causation evidence. Moreover, the reports in *Rider* were offered as the only evidence of causation linking the drug Parlodel with hemorrhagic stroke. (*See also, Soldo*; *Hollander v. Sandoz Pharmaceuticals Corp.*,289 F.3d 1193 (10th Cir. 2002); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 989 (8th Cir. 2001)). Defendant's cited cases are not on all fours with the issues before the Court.

Rule 403 requires that the probative value of evidence substantially outweigh the *unfair* prejudice such evidence may cause, not merely that it is detrimental to Defendant's case. "The damage done to the defense is not a basis for exclusion; the question under Rule 403 is 'one of "unfair" prejudice—not of prejudice alone.'" *Old Chief v. U.S.*, 519 U.S. 172, 192 (1997). Even more, unfairly prejudicial evidence is that which has, "an undue tendency to suggest decision on an improper basis." *Old Chief* at 193. The adverse event reports and complaint files do not unfairly suggest decision on an improper basis. The reports and complaints provide a wide-lensed view of the complications physicians around the country observed after implanting Mentor ObTape in women. The admission of the adverse event reports and complaint files demonstrate that Mentor had notice of complications, failed to investigate reports of complaints, failed to do proper testing, failed to recall ObTape, failed to fulfill their reporting requirements to the FDA, and failed to promulgate adequate warnings after observing the volume of complications after patients were implanted with ObTape.

E. <u>The Adverse Event Data In Both The Adverse Event Reports And Complaint Files Is Substantially Similar To Plaintiffs' Cases.</u>

Insofar as Defendant's MILs 8 and 9 attempt to limit Plaintiffs' evidence to only those incidents that are substantially similar, let this section serve as the response to MILs 8 and 9 as well. Plaintiffs have demonstrated substantial similarity. Each of the Plaintiffs' proffered adverse event reports and complaint files involve women implanted with the *same* device implanted through the *same* patented surgical route for treatment of the *same* medical condition as these

two Plaintiffs. Identical circumstances are not required, and it is difficult to discern how any greater similarity could be established in any products case.

While courts properly hold that the "substantially similar" standard should be relaxed when adverse event evidence is offered to show notice, e.g., *Jackson v. Firestone Tire & Rubber Co.*, 788 F.2d 1070, 1083 (5th Cir.1986), the relevant standard when adverse event evidence is admitted for purposes other than notice is "substantial similarity". Defendant states, "the proponent of such, [prior accident], evidence must show that 'conditions substantially similar to the occurrence caused the prior accidents.'" MIL 4 p. 7. However, "substantial similarity" turns on the nature of the product and the defect involved, and all of these reports and complaints involve the *same* product with the *same* claimed defect implanted with the *same* approach for treatment of the *same* medical condition and resulting in the *same* complications suffered by these Plaintiffs. To the extent that Mentor contends that there are any differences between any of the patients in the adverse event data and these two trial Plaintiffs in terms of its oft-asserted "patient" and "physician" factors, any such factors would "go merely to the weight to be given the [adverse data] evidence." *Jackson*, supra at 1083.

As demonstrated above, Plaintiffs do not proffer adverse event evidence solely for proof of causation, but also for several other purposes for which courts regularly admit such evidence. The cases upon which Mentor relies to support its "inadmissible for causation" argument (*McClain v. Metabolife* and *Rider v. Sandoz Pharmaceuticals*, etc.) are drug cases where the reported complications routinely occur in the absence of ingestion of the drug in question (i.e., they are "background risks"). In those cases, courts hold that just because persons taking the drug experienced the complication at issue does not establish scientific proof of causation by itself. In these cases, the erosions and infections reported in the adverse event reports and complaints were directly related to the product itself, and would not have occurred but for the implantation of the ObTape. Any "patient" or "physician" factors that Mentor claims could have

contributed to any particular patient's injury would not disprove causation. Further, the cases cited by Mentor instruct that courts can and do properly rely on adverse event evidence.[1]

Moreover, Mentor's well-worn defense of blaming the doctor and/or the patient, and never accepting responsibility for *any* injury suffered by any ObTape patient, actually provides a further basis for admission of Plaintiffs' adverse event reports and complaint files – both prior to and after the date of these Plaintiffs' implantations. It is the very fact that erosions and infections occurred in a "wide variety of patients" for whom Mentor marketed the ObTape – women with different medical histories and different doctors – that refutes Mentor's defense that any woman's particular medical history or her surgeon's skill or technique was to blame for her injuries. To refute Mentor's efforts to present these two trial Plaintiffs' injuries as the result of some anomalous doctor error or unusual patient susceptibility, Plaintiffs should be allowed to demonstrate to the jury that many doctors from around the world had patients who experienced the same problems as these two women.

When Mentor defends itself on the basis that "all tapes 'inherently' cause erosions and infections," Plaintiffs should be allowed to prove to the jury that in spite of its receipt of or knowledge of hundreds of complaints of ObTape-related erosions and/or infections, Mentor never conducted any scientific testing or investigation to determine or refute causation or to disprove defect with respect to any complaint. Instead, Defendant continued to subject women to this product. Plaintiffs should be allowed to expose before the jury the shortcomings of Mentor's causation defenses. *See, Dollar v. Long Mfg. N.C., Inc.*, 561 F.2d 613, 617 (5th Cir.1977) ("this Court has held that when causation is an issue, provided a proper foundation has been laid, evidence of subsequent accidents may be admissible to prove causation and to rebut the opposing party's causation theory."); *Weeks v. Remington Arms Co.*, 733 F.2d 1485, 1491 n. 10 (11th

[1] *See, e.g., McClain v. Metabolife Int'l., Inc.*, 401 F.3d 1233, 1253-54 (11th Cir.2005) (Although courts must consider that case reports are merely accounts of medical events, "the court may rely on anecdotal evidence such as case reports," and even though anecdotal reports alone cannot scientifically prove causation, "they may support other proof of causation….") (*quoting Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1199 (11th Cir.2002)).

Cir.1984) (Similar subsequent incidents may be used to "disprove a defendant's alternative theory of causation.").

III. CONCLUSION

Despite Mentor's contentions, the adverse event reports and complaint files offered by Plaintiffs are relevant and admissible for multiple purposes.

This 26th day of April, 2013.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2013, a true and correct copy of the foregoing document was served, via the Court's electronic filing system, to all counsel of record.

/s/ Richard N. Laminack
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